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02581-P0023A WJS/WWW

| International Application No. | PCT/DE96/02213 | |
|-------------------------------|--------------------------------|--|
| International Filing Date | November 20, 1996 | |
| Priority Date Claimed | November 20, 1995 | |
| Title of Application | Abrasive Or Cutting Instrument | |
| Applicants | Karl Storz, et al. | |

Assistant Commissioner for Patents Washington, DC 20231

Attention: EO/US

 \boxtimes

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

1. Applicants herewith submit to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:

This express request to immediately begin national examination procedures (35 U.S.C. 37(f)).

The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 CFR 1.492) as indicated below:

Express Mail Certificate: I hereby certify that this correspondence is today being deposited with the U.S. Postal Service as Express Mail Post Office to Addressee Mailing Label Number EM549542487US in an envelope addressed to: Assistant Commissioner for Patents; Washington, DC 20231.

May 20, 1998 ³

Bamar Enriou

NOTE: Documents and fees must be clearly identified as a submission to enter the National Stage under 35 USC 371 otherwise the submission will be considered as being made under 35 USC 111.37 CFR 1.494(f).

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2. Fees:

| CLAIMS FEE | (1) FOR | (2) NUMBER FILED | (3) NUMBER EXTRA | (4) RATE | (5) CALCULATIONS |
|---------------|--|---|---|---|---------------------|
| | TOTAL CLAIMS | 19 - 20 = | 0 | x \$22.00 = | \$.00 |
| | INDEPENDENT CLAIMS | 1 - 3 = | 0 | x \$82 = | .00 |
| | MULTIPLE DEPE | NDENT CLAIMS (i | f applicable) x \$270 |) | .00 |
| BASIC FEE | | | .00 | | |
| | has not Where been p | been paid (37 CF a search report repared by the Eur | 481(a)(2) R 1.492(a)(3) on the international opean Patent Office 192(a)(5)) | \$1,070.00 al application has e or the Japanese | 930.00 |
| | Patent Office (37 CFR 1.492(a)(5))\$ 930.00 TOTAL OF ABOVE CALCULATIONS = | | | 930.00 | |
| SMALL | Reduction by 1/2 | | entity, if applicable. | Affidavit must be | 00 |
| | Subtotal | | | 930.00 | |
| | Fee for recording (see Item 13 below | g the enclosed Asow). See attached | ssignment \$40.00 Assignment Cover | (37 CFR 1.21(h)) Sheet. | .00 |
| TOTAL | Total Fees enclos | sed | | | \$930.00 |

| \boxtimes | A check in the amount of \$930.00 is enclosed. |
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| | |

Please charge Account No. 19-4516 in the amount of \$.00.

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A copy of the International Application as filed is enclosed (35 U.S.C. 371 (c)(2)). 3. NOTE: Section 4.495(b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the international Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." is transmitted herewith. is not required as the application was filed with the United States Receiving Office. has been transmitted: by the International Bureau. The date of mailing of the application (from M form PCT/IB/308): 29 May 1997 by applicant on ---. A translation of the International application into the English language (35 U.S.C. 371 (c)(2): is transmitted herewith. is not required as the application was filed in English. was previously transmitted by applicant on ---. will follow. Amendment to the claims of the International Application under PCT Article 19 (35 U.S.C. 5. 371(c)(3)): NOTE: The Notice of January 7, 1993 points out that 37 CFR § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 Amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendment. Applicant may submit that subject matter in a preliminary amendment filed under Section 1.121. In many cases, filing an amendment under Section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36. is transmitted herewith. has been transmitted: by the International Bureau. The date of mailing of the amendment (from form PCT/IB/308): ---. by applicant on ---. has not been transmitted as: applicant chose not to make amendment under PCT Article 19. The X date of the Mailing of the Search Report (from form PCT/ISA/210):05/22/97. the time limit for the submission of amendments has not yet expired. The amendment or a statement that amendments have not been made will be transmitted before the expiration of the time limit under

PCT Rule 46.1.

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| 6. | A trans | lation of the amendment to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)): |
|-----|---------|--|
| | | is transmitted herewith. is not required as the amendments were made in English. was not transmitted for reasons indicated at point 5 above. will follow. |
| 7. | A copy | of the international examination report (PCT/IPEA/409): |
| | | is transmitted herewith. is not required as the application was filed with the United States Receiving Office. |
| 8. | Annex | (es) to the International Preliminary Examination Report: |
| | | is/are transmitted herewith. is/are not required as the application was filed with the United States Receiving Office. |
| 9. | A tran | slation of the annexes to the International Preliminary Examination Report: |
| | | is transmitted herewith. is not required as the application was filed with the United States Receiving Office. |
| 10. | An oa | th or declaration of the inventor (35 U.S.C.(c)(4)) complying with 35 U.S.C 115: |
| | | was previously submitted by applicant on is submitted herewith, and such oath or declaration: |
| | | is attached to the application. identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3b or 3c and 5b; and states that they were reviewed by the inventor as required by 37 CFR 1.70. ⋈ will follow. |
| 11. | An In | ernational Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a): |
| | | is transmitted herewith. has been transmitted by the International Bureau. The date of mailing from form PCT/IB/308): is not required, as the application was searched by the United States International Searching Authority. will be transmitted promptly upon request. has been submitted by applicant on |

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| 12. | An Information Disclosure Statement under 37 CFR 1.97 and 1.98: | | | |
|-----|---|---|--|--|
| | | is transmitted herewith. Also transmitted herewith is/are: | | |
| | | Form PTO-1449. Copies of the citations listed. | | |
| | \boxtimes | will be transmitted within three months of the date of submission of requirements under 35 U.S.C. 371(c). | | |
| | | was previously submitted by applicant on | | |
| 13. | Additio | onal Documents being transmitted: | | |
| | \boxtimes | Copy of Request (PCT/RO/101). International Publication No. WO 97/18745. Specification, claims and drawings | | |
| | \boxtimes | Front page only. Preliminary Amendment (37 CFR §1.121). | | |
| 14. | | An Assignment document: | | |
| | | is transmitted herewith for recording. A separate Cover Sheet for Assignment Accompanying New Patent Application is attached. | | |
| | ⊠ Wi | I follow. | | |
| 15. | The a | bove-checked items are being transmitted: | | |
| | | before 30 months from any claimed priority date. after 30 months. | | |
| 16. | Certai name | n requirements under 35 USC were previously submitted by the applicant on, y: | | |

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Authorization to Charge Additional Fees

The Commissioner is hereby authorized to charge **any** additional fees, including, but not limited to 37 CFR 1.492(a)(1),(2),(3)&(4) (filing fees) and 37 CFR 1.492(b),(c),(d) (presentation of extra claims) by this paper and during the entire pendency of the Application to Account No. 19-4516.

Respectfully submitted,

May 20, 1998

William J. Speranza, Registration No., 26,340 Wesley W. Whitmyer, Jr., Registration No. 33,558

Attorneys for Applicants

ST.ONGE STEWARD JOHNSTON & REENS LLC

986 Bedford Street

Stamford, CT 06905-5619

203 324-6155

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PATENT 02581-P0023A WJS/WWW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| Applicants | Karl Storz, et al. | |
|----------------------|--------------------------------|--|
| Serial No Pending | Filing Date: May 20, 1998 | |
| Title of Application | Abrasive Or Cutting Instrument | |
| Group Art Unit | Examiner | |

Assistant Commissioner for Patents Washington, DC 20231

Preliminary Amendment

Dear Sir:

Kindly enter this preliminary amendment before calculating the filing fee for this case.

In the Claims

1. (Amended) An [Abrasive or cutting] instrument comprising a tube with a rotating blade [having and abrasive or cutting region] at [its] a distal end of said tube, and adapted for al, which is connected via a tube to the] drive unit [disposed] at a [in the] proximal [region] end of the instrument, [with] a suction passage [being] provided in said tube for exhausting tissue particles, and [characterized in that] an [additional] irrigation passage [is] provided in said tube through which an irrigation liquid is passed to the distal end for cleaning the blade and for assistance in exhausting [the severed or abraded] tissue particles.

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May 20, 1998

Beatrice R. Emerson

Ramak Enrison

Applicant: Karl Storz, et al.

May 20, 1998

3. (Amended) Instrument according to Claim 1 [or 2],

characterized in that a handpiece is provided in which [said] <u>a</u> drive unit is accommodated.

4. (Amended) Instrument according to [any of the Claims 1 to 3] <u>Claim 1</u>, **characterized** in that [a rotating inner blade and] a stationary [outer] blade [are] is provided <u>outside the rotating blade</u>.

5. (Amended) Instrument according to Claim 4, characterized in that the gap between said [inner] stationary blade and said [outer] rotating blade constitutes the irrigation passage.

6. (Amended) Instrument according to Claim [4] 1, characterized in that said irrigation passage is disposed in the instrument[s] in a non-symmetrical arrangement.

7. (Amended) Instrument according to Claim [6] <u>5</u>, **characterized** in that said irrigation passage is disposed on said outer blade.

8. (Amended) Instrument according to [any of the Claims 1 to 4] <u>Claim 1</u>, **characterized** in that a hollow shaft is provided into which said blade and the tube attached thereto are inserted so as to form said irrigation passage between said tube and said shaft.

10. (Amended) Instrument according to Claim 8 [or 9], characterized in that said hollow shaft is [detachable] detachably fastened on said handpiece.

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11. (Amended) Instrument according to [any of the Claims 1 to 10] <u>Claim 1</u>, **characterized** in that the irrigation liquid passed through said irrigation passage is exhausted through said suction passage without entering the body cavity into which the instrument is introduced.

- 12. (Amended) Instrument according to [any of the Claims 1 to 11] <u>Claim 1</u>, **characterized** in that said suction passage is flared from the distal towards the proximal end.
- 13. (Amended) Instrument according to [any of the Claims 1 to 12] <u>Claim 8</u>, characterized in that [the abrasive or] <u>a</u> cutting region is provided laterally on said blade, and that [the] <u>a</u> face of said hollow shaft extends obliquely along the direction of [the] <u>a</u> longitudinal axis.
- 14. (Amended) Instrument according to Claim [13] 1, characterized in that [the] a discharge opening for the irrigation liquid is so designed that at least [the] a bulk volume of the irrigation liquid is discharged in [the] a region which does not serve for [abrasion or] cutting.
- 15. (Amended) Instrument according to [any of the Claims 1 to 14] <u>Claim 1</u>, **characterized** [in that the] <u>by providing</u> [proximally] <u>proximal</u> [provided] connectors for said suction and irrigation passages [are coaxially designed].
- 16. (Amended) Instrument according to [any of the Claims 1 to 14] <u>Claim 15</u>, **characterized** in that the proximally provided connectors for said suction and irrigation passages are configured to be adjacent to each other.

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17. (Amended) Instrument according to [any of the Claims 1 to 14] <u>Claim 15</u>, **characterized** in that the proximally provided [fitting] <u>connector</u> for said irrigation passage extends at an angle of 90° relative to [the] <u>a</u> longitudinal instrument axis.

18. (Amended) Instrument according to Claim 15,

characterized in that said irrigation passage is provided ahead of the handpiece, seen in a direction towards the proximal end, so that the outer blade will be rotatable relative to the handpiece.

Please add the following claim.

19. Instrument according to Claim 15,

characterized in that the proximally provided connectors for said suction and irrigation passages are configured coaxial with respect to each other.

REMARKS

The revised claims are substantially the same as those in the application as filed.

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May 20, 1998

The amendments eliminate multiple dependencies, correct antecedent basis, eliminate unnecessary limitations, and otherwise conform the claims to U.S. Practice.

Respectfully submitted,

W. Whit your

William J. Speranza, Registration No., 26,340

Wesley W. Whitmyer, Jr., Registration No. 33,558

Attorneys for Applicants

ST. ONGE STEWARD JOHNSTON & REENS LLC

986 Bedford Street

Stamford, CT 06905-5619

203 324-6155

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Abrasive or Cutting Instrument

Description

Field of the invention

The present invention relates to an abrasive or cutting instrument with a rotating blade having an abrasive or cutting region at its distal end in accordance with the introductory clause of Patent Claim 1.

Such abrasive or cutting instruments, which are also termed scrapers or rasps, are employed in endoscopic surgery, e.g. in micro arthroplasty operations.

Prior art

Shaving or cutting instruments of the claimed general type include at least one blade which is rotated at a speed of up to 1,600 or more revolutions per minute. To this end the blade is connected via a shaft to a motor accommodated in the proximal section of the instrument.

The shaft may be a hollow shaft. The passage formed by this configuration is connected to a suction opening in the face area of the blades, which present normally a cylindrical configuration. In this manner it is possible to exhaust liquid and severed tissue particles through the blade.

The known removal or cutting instruments involve, however, the problem that abraded or cut-off tissue particles may adhere to the blade and hence induce the risk of soiling, of blade "clogging" and/or transfer of tissue particles.

Brief description of the invention

The present invention is based on the problem of improving an abrasive or cutting instrument in accordance with the introductory clause of Claim 1 in a way that tissue particles will be prevented from adhering to the blade.

One inventive solution to this problem is defined in Patent Claim 1. Improvements of the invention are the subject matters of the Claims 2 et seq.

In accordance with the invention an additional irrigation passage is provided through which an irrigation or flushing liquid is passed to the distal end for cleaning the blade and for assistance in exhausting the severed or abraded tissue particles. It is preferred that the irrigation liquid does not enter the body cavity into which the instrument is introduced but is rather exhausted again immediately after it has rinsed and thus cleaned the blade (Claim 11).

The inventive instrument is thus suitable for application not only in organs filled with an irrigating liquid, as is the case in arthroscopy, but also in body regions which can or should not be filled with the irrigating liquid. The inventive instrument can hence be used in ENT surgery, e.g. in the region of the nasal cavity.

The irrigation passage, which is provided in accordance with the invention, does not only serve to clean the blade but it reduces also the risk of clogging in exhaust passages with small lumina which present a typical inside diameter of 1 to 3 mm in ENT applications.

In the improvement defined in Claim 2 the suction passage is centrally arranged. There the suction passage may be provided particularly in the drive tube of the rotating blade.

In accordance with Claim 3 a handpiece is provided which receives the drive unit and is designed, in particular, in a way that the operator will be able to use the inventive instrument in an ergonomic way.

The basic inventive idea to provide an additional irrigation passage in an abrasive or cutting instrument of the claimed general type may be applied, on principle, in instruments of any configuration whatsoever, e.g. in instruments provided only with a rotating blade. The fundamental inventive idea is particularly expedient, however, in instruments provided with a rotating inner blade and a stationary outer blade (Claim 4). With these instruments it happens especially frequently that severed tissue particles become stuck in the narrow gap between the inner and outer blades. The Claims 5 to 8 define various alternatives of the arrangement of the irrigation passage. For instance, the gap between the inner and outer blades may constitute the irrigation passage. This configuration presents the advantage that the gap is thus cleaned with a particularly high efficiency even though the increased expenditure in terms of structure might be a disadvantage. The alternatives defined in Claims 6 and 7 have a design which is comparatively simple to realise.

In the solution defined in Claim 8 a hollow shaft is provided into which the blade and the tube attached to it are so inserted that the irrigation passage is formed between the tube and the shaft. This solution does not only result in an instrument which is very easy to clean and to sterilise in particular but it permits also the retrofitting of existing instruments of the claimed general type.

In such a design the hollow shaft is preferably arranged in a way that the irrigation passage surrounds the blade and the tube in coaxial relationship (Claim 9). The improvement set forth in Clam 10, according to which the hollow shaft is detachably fastened on the handpiece, substantially facilitates the cleaning of the instrument.

The clogging risk is further reduced with a suction passage flaring from the distal end towards the proximal end (Claim 12).

The fundamental inventive ideas may preferably be applied in an instrument in which the abrasive or cutting section is disposed laterally of the blade in a manner known per se, and in which the face of the hollow shaft extends obliquely along the direction of the longitudinal axis. The risk of blade clogging is particularly high in the known instruments of this type when there is no irrigation passage. In such an instrument the provision is moreover preferred that the outlet opening for the discharge of the irrigation liquid is so configured that at least the bulk volume of the irrigation liquid will be discharged in the region which is not used for abrasion or cutting (Claims 14 and 15).

The Claims 15 to 17 describe various alternatives of the connectors which are provided at the proximal end for connection of the suction and irrigation passages.

In the version in which the proximally disposed irrigation passage connector forms an angle of 90° relative to the longitudinal instrument axis (Claim 17) it is preferred that the irrigation passage connector is provided ahead of the handpiece, seen in a direction towards the proximal end, so that the outer blade will be rotatable relative to the handpiece.

Brief description of the drawings

The invention will be described in more details by exemplary embodiments in the following, with reference to the drawing wherein:

Figure 1a is a cross-sectional view of a first embodiment of an inventive instrument;

Figures 1b and 1c show alternatives of the arrangement of the irrigation passage;

Figure 2a is a cross-sectional view of a second embodiment of an inventive instrument:

Figure 3 shows the proximal region of a third embodiment of the invention.

Description of embodiments

The inventive instrument illustrated in Figure 1a comprises an inner blade 1 and an outer blade 2 in a manner known per se. The outer blade 2 is stationary and in the embodiment shown here it is connected to a proximal body portion 4 of the instrument. The inner blade 1 is connected via a tube 5 supported for rotation to a drive unit which is not illustrated here and which rotates the inner blade 1 relative to the main body portion 4 and hence to the stationary outer blade 2. A suction or exhaust passage 6 is provided in the tube 5, which is connected by its distal end to an appropriate suction pump not illustrated here.

In the embodiment shown here an additional irrigation passage is provided through which an irrigation pump (not illustrated) pumps an irrigation liquid from a fit-

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ting 7 to the distal end. In the embodiment illustrated here the irrigation passage 8 is mounted on the tube 3 of the outer blade 2. Figures 1b and 1c, which illustrate a section taken at A-A in Figure 1a, represent two possibilities for the arrangement of the irrigation passage 8.

Figure 2a shows an alternative of the arrangement of the irrigation passage 8, with identical parts being identified by the same reference numerals as in Figure 1. In the embodiment shown in Figure 2a the irrigation passage 8 surrounds the tube 5 of the inner blade 1 in coaxial relationship Figures 2b and 2c show each a sectional view taken at A-A and B-B in Figure 2a.

Figure 3 is a view of the proximal region of an embodiment in which the fitting 7 for the irrigation passage is not disposed in parallel with the longitudinal instrument axis but at an angle of 90° relative to the longitudinal axis. The fitting 7, which may be designed as Luer lock fitting, for instance, is arranged here in a part 9 separated from the remaining instrument so that it may be rotated about the longitudinal instrument axis. The reference numeral 10 indicates schematically the handpiece with the motor for driving the inner blade.

The abrasive or cutting instrument with the inventive configuration is suitable for application in the same manner as conventional instruments in combination with the common endoscopic instruments.

PATENT CLAIMS

1. Abrasive or cutting instrument with a rotating blade having an abrasive or cutting region at its distal end, which is connected via a tube to the drive unit disposed in the proximal region of the instrument, with a suction passage being provided in said tube,

characterised in that an additional irrigation passage is provided through which an irrigation liquid is passed to the distal end for cleaning the blade and for assistance in exhausting the severed or abraded tissue particles.

- Instrument according to Claim 1,
 characterised in that said suction passage is centrally arranged.
- 3. Instrument according to Claim 1 or 2, characterised in that a handpiece is provided in which said drive unit is accommodated.
- 4. Instrument according to any of the Claims 1 to 3, characterised in that a rotating inner blade and a stationary outer blade are provided.
- 5. Instrument according to Claim 4, characterised in that the gap between said inner blade and said outer blade constitutes the irrigation passage.
- 6. Instrument according to Claim 4, characterised in that said irrigation passage is disposed in the instruments in a non-symmetrical arrangement.
- 7. Instrument according to Claim 6, characterised in that said irrigation passage is disposed on said outer blade.

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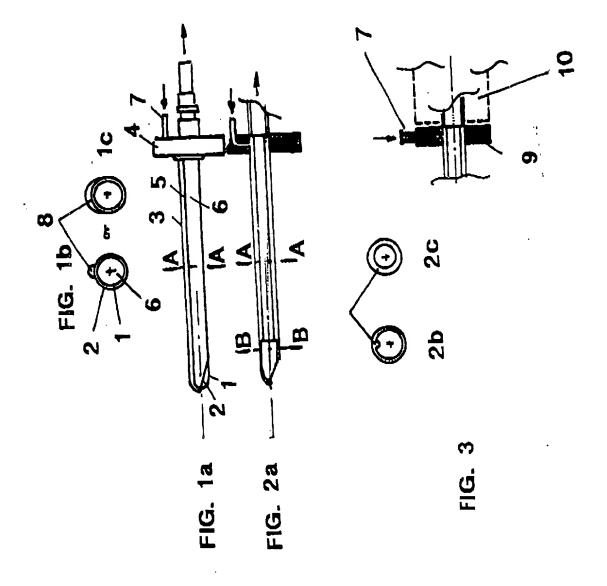
- 8. Instrument according to any of the Claims 1 to 4, characterised in that a hollow shaft is provided into which said blade and the tube attached thereto are inserted so as to form said irrigation passage between said tube and said shaft.
- 9. Instrument according to Claim 8, characterised in that said irrigation passage surrounds said blade and said tube in a coaxial relationship.
- 10. Instrument according to Claim 8 or 9, characterised in that said hollow shaft is detachable fastened on said handpiece.
- 11. Instrument according to any of the Claims 1 to 10, characterised in that the irrigation liquid passed through said irrigation passage is exhausted through said suction passage without entering the body cavity into which the instrument is introduced.
- 12. Instrument according to any of the Claims 1 to 11, characterised in that said suction passage is flared from the distal towards the proximal end.
- 13. Instrument according to any of the Claims 1 to 12, characterised in that the abrasive or cutting region is provided laterally on said blade, and that the face of said hollow shaft extends obliquely along the direction of the longitudinal axis.
- 14. Instrument according to Claim 13, characterised in that the discharge opening for the irrigation liquid is so designed that at least the bulk volume of the irrigation liquid is discharged in the region which does not serve for abrasion or cutting.

- 15. Instrument according to any of the Claims 1 to 14, characterised in that the proximally provided connectors for said suction and irrigation passages are coaxially designed.
- 16. Instrument according to any of the Claims 1 to 14, characterised in that the proximally provided connectors for said suction and irrigation passages are configured to be adjacent to each other.
- 17. Instrument according to any of the Claims 1 to 14, characterised in that the proximally provided fitting for said irrigation passage extends at an angle of 90° relative to the longitudinal instrument axis.
- 18. Instrument according to Claim 17,

characterised in that the connector for said irrigation passage is provided ahead of the handpiece, seen in a direction towards the proximal end, so that the outer blade will be rotatable relative to the handpiece.

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Page 2 Declaration and Power of Attorney Karl Storz, et al.

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint William J. Speranza, Registration No. 26,340, and Wesley W. Whitmyer, Jr., Registration No. 33,558, of ST.ONGE STEWARD JOHNSTON & REENS LLC; 986 Bedford Street; Stamford, Connecticut 06905-5619 (203 324-6155); with full power of substitution, association and revocation, as attorney to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please direct all telephone calls and correspondence to Wesley W. Whitmyer, Jr., at the above address and telephone number.

Full name of first inventor: Karl Storz (deceased)

Date: June 12, 1998

By Lybill Hay Reling
Sybill Storz-Reling, Executrix

Residence:

D-78532 Tuttlingen

GERMANY

Citizenship:

A citizen of Germany

Post Office Address:

Schwabstrasse 28 D-78532 Tuttlingen

GERMANY

Declaration and Power of Attorney Karl Storz, et al.

Th)

Full name of second inventor:

Inventor's signature

Date:

Residence:

Citizenship:

Post Office Address:

Pavel Novak

Nay 28, 1998

CH-8207 Schaffhausen, Switzerland

A citizen of Switzerland

Stettemerstrasse 177

CH-8207 Schaffhausen, Switzerland

100

Ü

Full name of third inventor:

Inventor's signature

Date:

Residence:

Citizenship:

Post Office Address:

Simon Solingen

Los Angeles, CA 90077

A citizen of the United States

2927 Woodwardia Dr. Los Angeles, CA 90077

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DECLARATION AND POWER OF ATTORNEY

As below-named inventors, we hereby declare that:

Our residences, post office addresses, and citizenships are as stated below next to our names.

We believe that we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled **Abrasive Or Cutting Instrument** (File No. 02581-P0023A WJS/WWW).

We hereby state that we have reviewed and understand the contents of the aboveidentified specification, including the claims, as amended by any amendment referred to above. To the best of our knowledge, information, and belief the facts stated therein are true.

We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign applications for patent or inventor's certificate listed below and have also identified below any foreign applications for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

German Application No. DE 195 43 259.2 Filed November 20, 1995 German Application No. DE 196 33 124.2 Filed August 16, 1996

We hereby claim the benefit under Title 35, United States Code, §120 of the following United States Applications listed below, and insofar as the subject matter of each of the claims of this Application is not disclosed in the prior United States Application in the manner provided by the first paragraph of Title 35, United States Code, §112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

None

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false